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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,330	03/25/2004	**Eitan Konstantino**	021770-000120US	8217

20350 7590 12/22/2008

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EXAMINER	
NGUYEN, VI X	
ART UNIT	**PAPER NUMBER**
3734	
MAIL DATE	**DELIVERY MODE**
12/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,330	KONSTANTINO ET AL.	
	Examiner	Art Unit	
	Victor X. Nguyen	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-64,69 and 70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60-64,69 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/17/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The request filed on 10/27/2008 for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/810,330 is acceptable and a RCE has been established. An action on the RCE follows.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 60-64 and 69-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US 2002/0010487) in view ofDror et al (5,102,402).

Evans et al disclose in figures 2-4, a method for collecting, and removing thrombus from blood vessels, including: scoring the lesion with a scoring structure 19 comprising metal scoring elements 30 which carried by an expansible balloon (see paragraph 68 and 80), and wherein the balloon is expanded to engage the scoring elements against stenotic material in the lesion to cut the stenotic material (see paragraph 65 and 82). Regarding to the recitation a method of delivering a drug to a blood vessel lesion has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190

USPQ 15 (CCPA 1976) andKropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478,481 (CCPA 1951).

Evans is silent regarding the step of releasing a drug into the lesion and inflating a balloon to radially expand.

Dror teaches the step of releasing a drug into the lesion (see col. 2, lines 7-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Evans by releasing a drug into the lesion as taught by Dror in order to produce affecting drugs or diagnostic materials exactly where it is needed. *It would have further been obvious to one having ordinary skill in the art at the time the invention was made to reverse the balloon to be deployed in combination with the shearing baskets 18,20 for radially expanded, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.*

Evan further teaches wherein the metal scoring elements are included in a scoring cage slidably carried to the expansible balloon (see figs. 2, 4). At best in fig. 4, Evan teaches the scoring elements in the scoring cage which are arranged helically over the balloon. As to claims 61-64, Dror teaches the drug is carried by the balloon 12 as a platform, where the drug is present in capsules 16 or in a drug containing polymer (see col. 2, line 11).

Response to Arguments

3. Applicant's arguments filed 10/27/2008 have been considered but they are not persuasive. Applicant states that Evan reference does not teach inflating a balloon to radially expand a scoring structure. Examiner disagrees. It is noted that figures 2-4 of Evan teaches a cage structure 28 comprising a pair of helical blades 18,20. These blades do have some sort of

radially expanded in combination with a balloon (see paragraph 80 and the above comment regarding to "reversal of parts" rejection). Furthermore, the applicant argues that Dror reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., **the drugs would necessarily be in liquid** in order to be mixed by the shearing blades…) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In fact in Applicant's claim 63 does recite "the drug is present in capsules". Furthermore, Dror teaches the drug is carried by the balloon 12 as a platform, where the drug is present in capsules 16 or in a drug containing polymer (see col. 2, line 11).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ho Jackie can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

/Victor X Nguyen/
Examiner
Art Unit 3734

VN